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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,713	06/12/2001	Ruedi Aebersold	39-00	5526

23713 7590 01/20/2004

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5370 MANHATTAN CIRCLE
SUITE 201
BOULDER, CO 80303

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/20/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,713

Applicant(s)

AEBERSOLD ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-41,43-52,68-71 and 74-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-21,41,43-45,68,69,74-77⁸⁰ and 81 is/are allowed.
- 6) ☒ Claim(s) 22,29-40,46-52,70,71 and 78 is/are rejected.
- 7) ☒ Claim(s) 23-28 and 79 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on June 12, 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2) Claims 22, ~~23~~, 29-40, 46-52, 70, 71, and 78 are rejected under 35 U.S.C. 112, first paragraph, as *i)* failing to comply with the written description requirement and *ii)* failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons set forth in paragraph **4)b)** of the May 05, 2003 Office action.

Applicant's arguments filed November 05, 2003 have been fully considered but they are not persuasive. Applicant's statement that "the Office Action gives no explanation as to why the clear statements in the specification accompanied by concrete examples would not be understood by one of ordinary skill in the art that the inventors had possession of the invention as claimed in claim 22" ignores the discussion of paragraph **4)b)** of the Office action. Specifically, the description of page 7, lines 1-17 and page 10, lines 23 *et seq* provides the only written description of the method of claim 22 and applicants have not disputed this fact. This description does not describe how the step is to be performed which "selectively protects the carboxylic acid groups or esters thereof...such that any phosphate groups...remain unprotected". The remainder of the specification clearly describes and requires that both the phosphate and carboxylic acid groups of the peptide or protein be protected (claim 1, step a.) followed by selective cleavage of the phosphoramidate bonds (claim 1, step b.); this combination of steps as recited in claim 1 is different from the combination of steps recited in claim 22 wherein the phosphate groups remain unprotected. While the specification describes the details of performing the method of claim 1, no such description is present for the method of claim 22. Although

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applicants state that "one of ordinary skill in the art in view of the teachings and examples provided could by routine testing of known reagents identify reagents in addition to those exemplified to carry out the selective labeling as claimed in claim 22", the specification does not support this conclusion. There are no reagents "exemplified" which would differentially protect the carboxylic acid groups while leaving the phosphate groups unreacted and there are no "examples" provided to assist one of ordinary skill in the art in choosing "known reagents" which would be useful in the practice of the method of claim 22.

While applicants state that "the two step method of claim 1 is one example of a method that can be used to selectively label (protect?) carboxylic acid groups...and regenerate free phosphate groups" (Remarks, page 22, second paragraph), the method of claim 22 does not require the particulars of step a. of claim 1, namely the simultaneous protection of both the carboxylic acid and phosphate groups using an amine reactant. Thus, claim 1 cannot be used to support the method of claim 22.

3) Claims 23-28 and 79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4) Claims 1, 3-21, 41, 43-45, 68, 69, 74-77, 80 and 81 are allowed.

5) THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

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date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

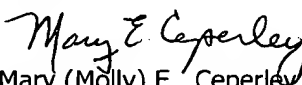
6) Applicant is advised that form PTO-948 is based on a review of the copies of the drawings which are presently available in the file. The objection to the right margin of the drawing of Fig. 1 may not be applicable to the original drawing.

7) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (703) 308-4239. After January 27, 2004 the examiner's telephone number will be (571)272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (703) 305-3399. The central fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

January 13, 2004


Mary (Molly) E. Ceperley
Primary Examiner
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